SPL at FDA: A Progress Report

Lisa L. Stockbridge, Ph.D.

March 30, 2006

FDA

Implementation – October 31, 2005

- Content of labeling in SPL (xml) only
- SPL submitted in an electronic folder entitled "SPL"
- One SPL per submission
- Negotiations in WORD
- Formatted label examples in pdf
- Whole label to be submitted
- Submission vehicle = Annual Report
    - Current SPL submitted on anniversary
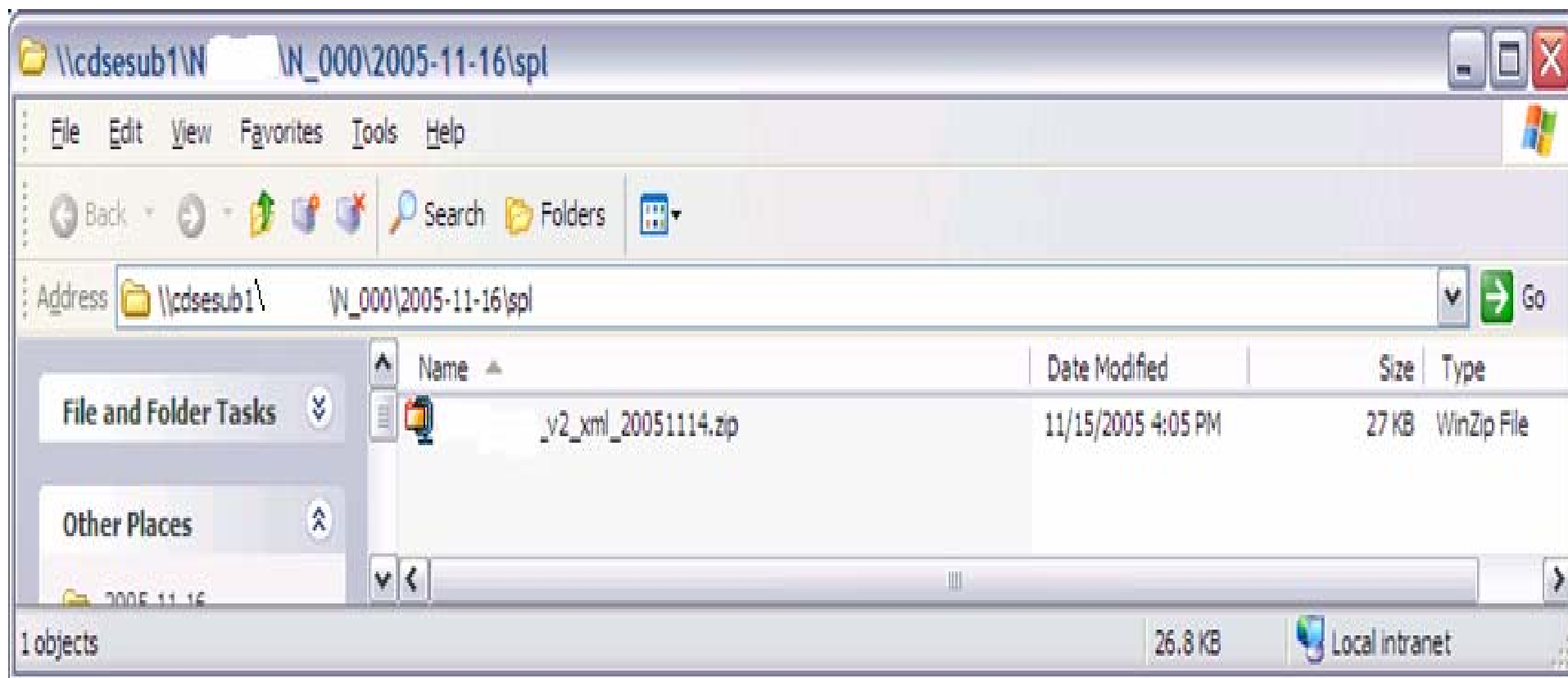
834 *SPL Successfully Loaded*

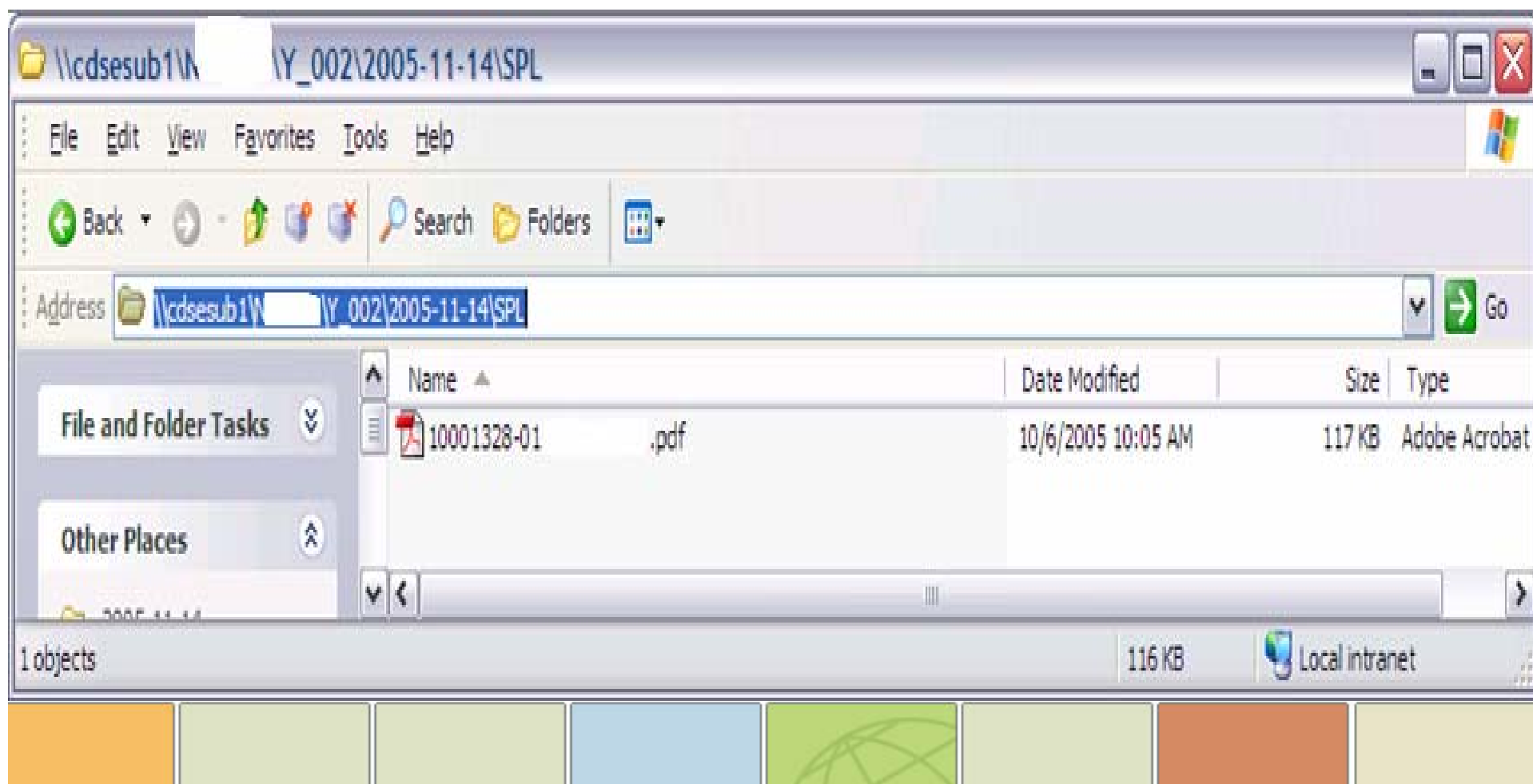*(November 1, 2005 – March 21, 2006)*

Common SPL Failures

- 51% Did not parse against schema
- 16% No XML SPL document in folder
- 12% No SPL folder
- 11% More than one XML document in folder
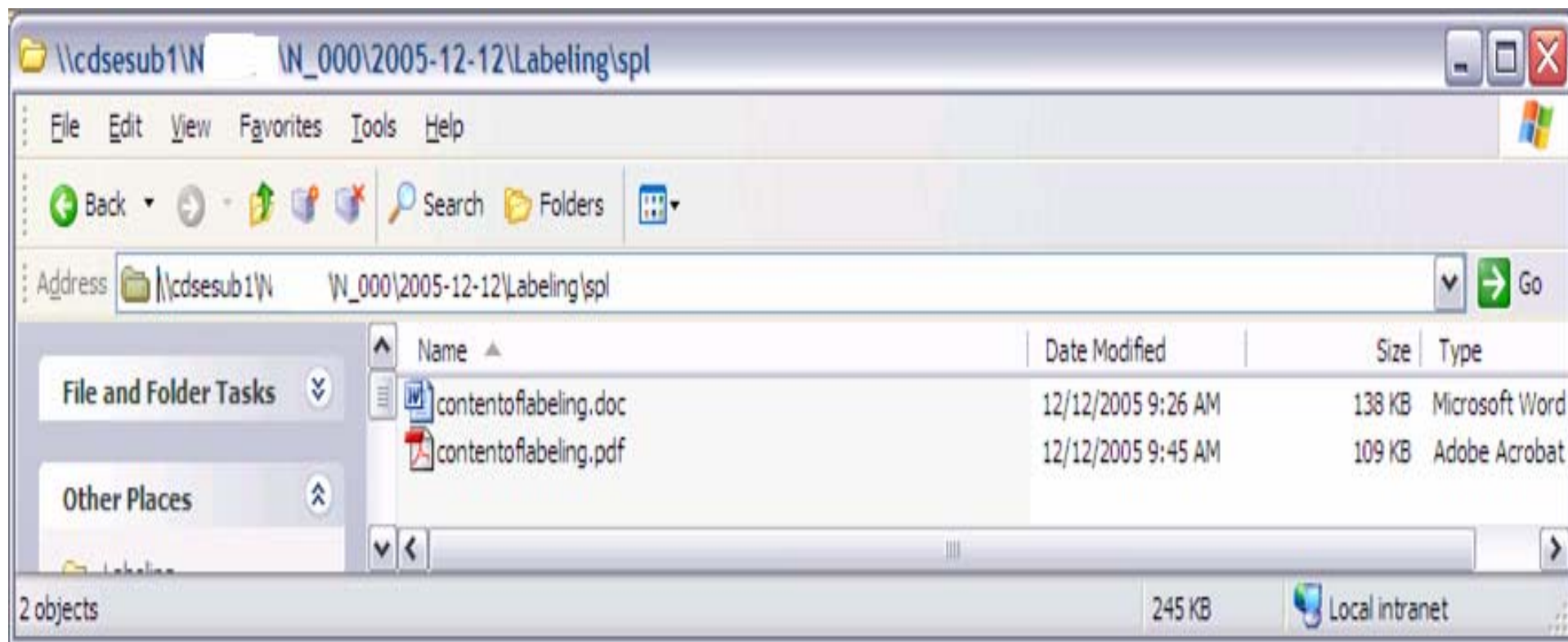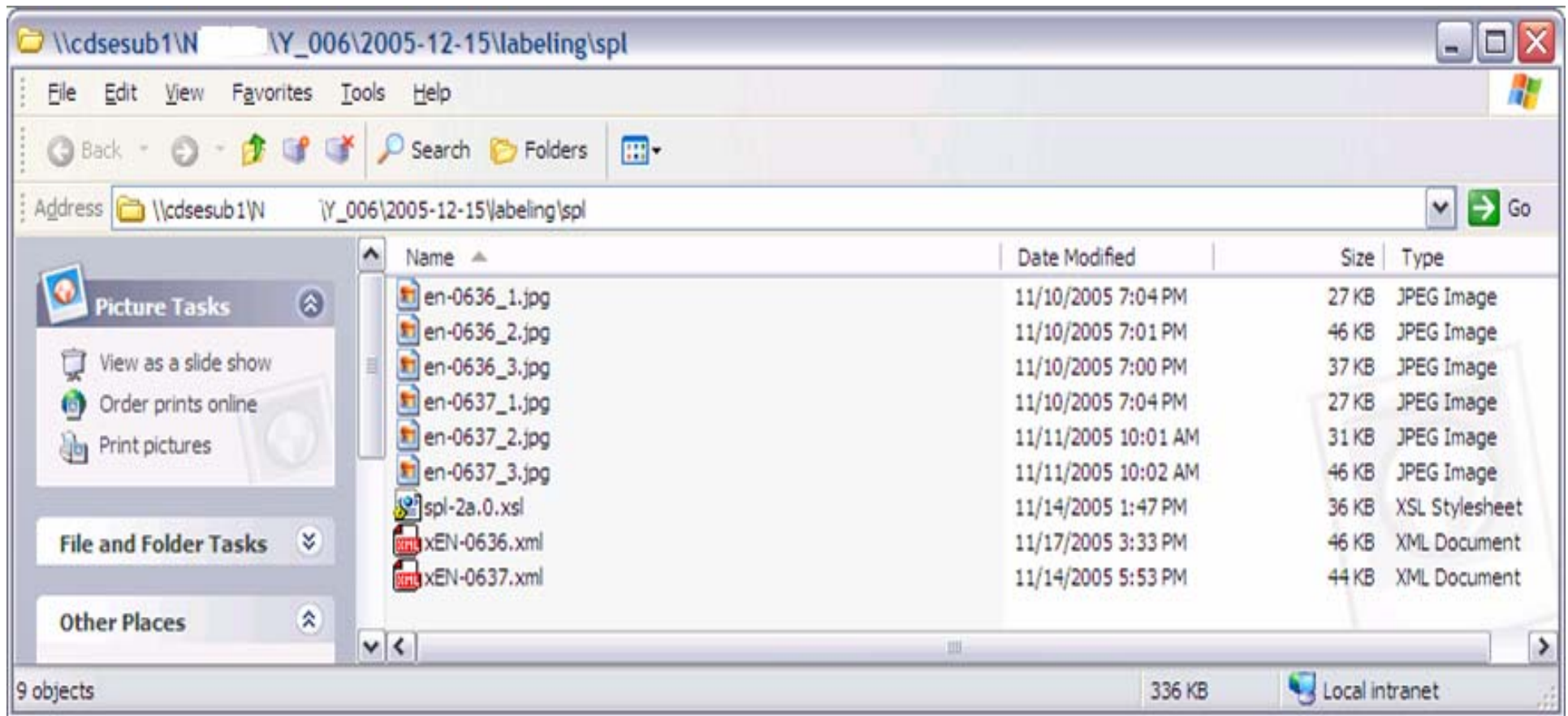- 10% Other reasons (including invalid DocID, SETID)

No SPL in the folder at all
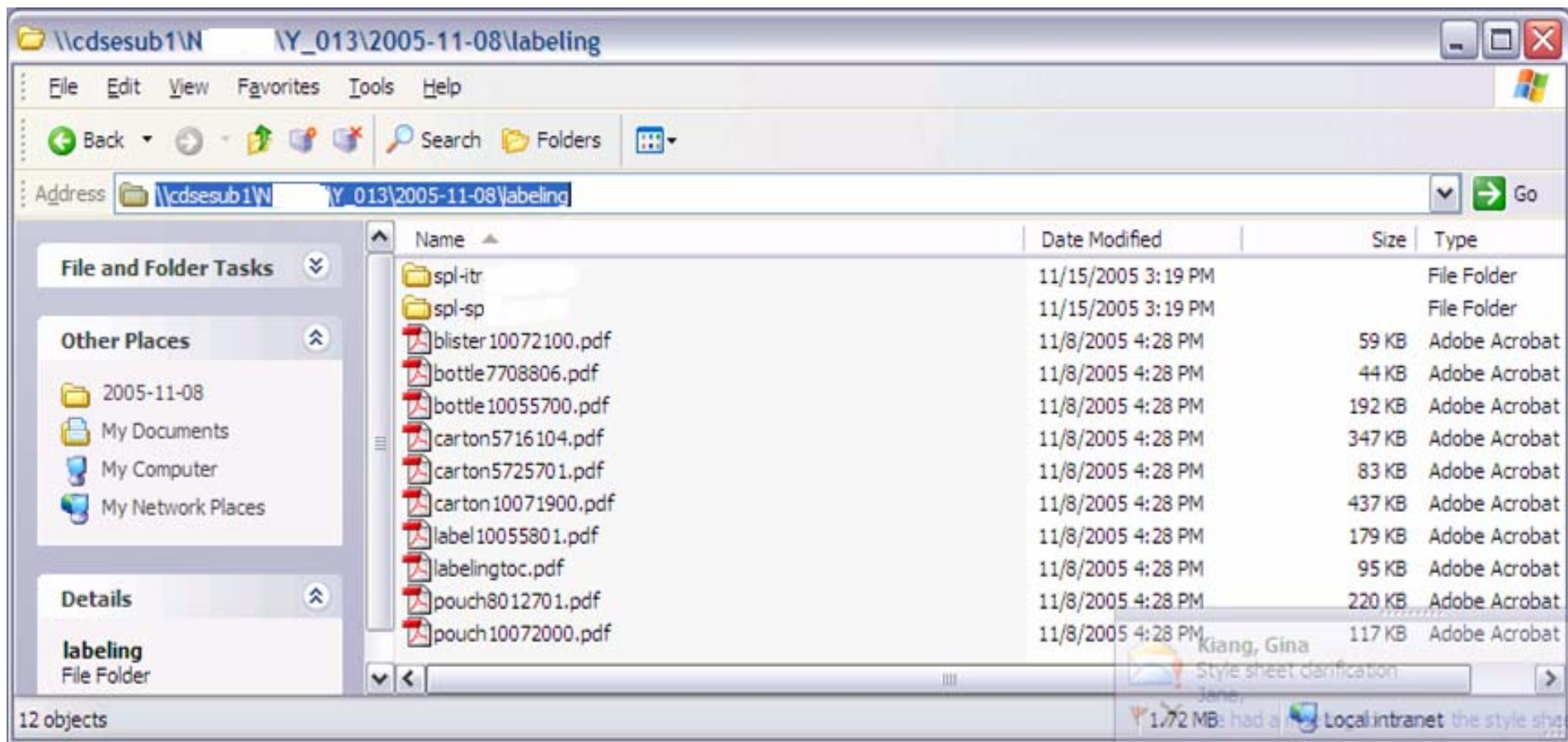
No XML SPL in the folder – pdf instead

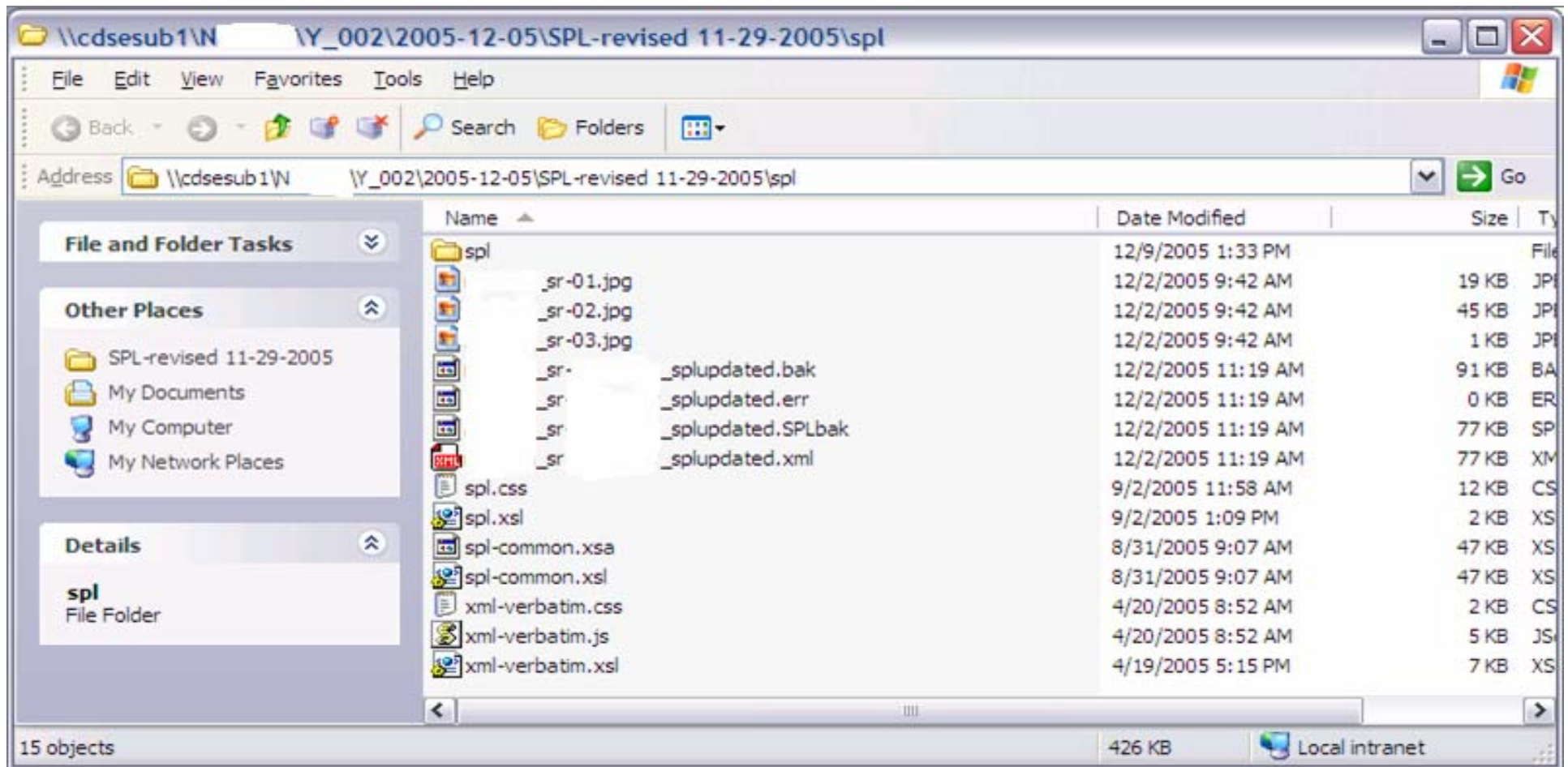# No XML SPL in the folder – pdf and doc instead

More than one SPL in the folder

More than one SPL folder

SPL folder within a folder

Notification of Failure to Load

- Fax to sponsor with explanation

- Website link(s) for clarification

- Direction as to whether resubmission is required
  or FDA is able to repair

- Contact information for further assistance

Contact with Labeling Coordinator

- Errors that require information from sponsor include

  - Tablet size

  - Imprint information

  - Other characteristics of product

- SPL errors that require rework include

  - Poorly constructed SPL

  - Package within a package

- dailymed.nlm.nih.gov

- Downloadable files (ftp) for posted SPL

- Stylesheet issues

  - Format vs. content

The Electronic Labeling Rule requires that the content of labeling be submitted in SPL. The stylesheet dictates how the content will look.

Progress Report – Summary

(November 1, 2005 – February 28, 2006)
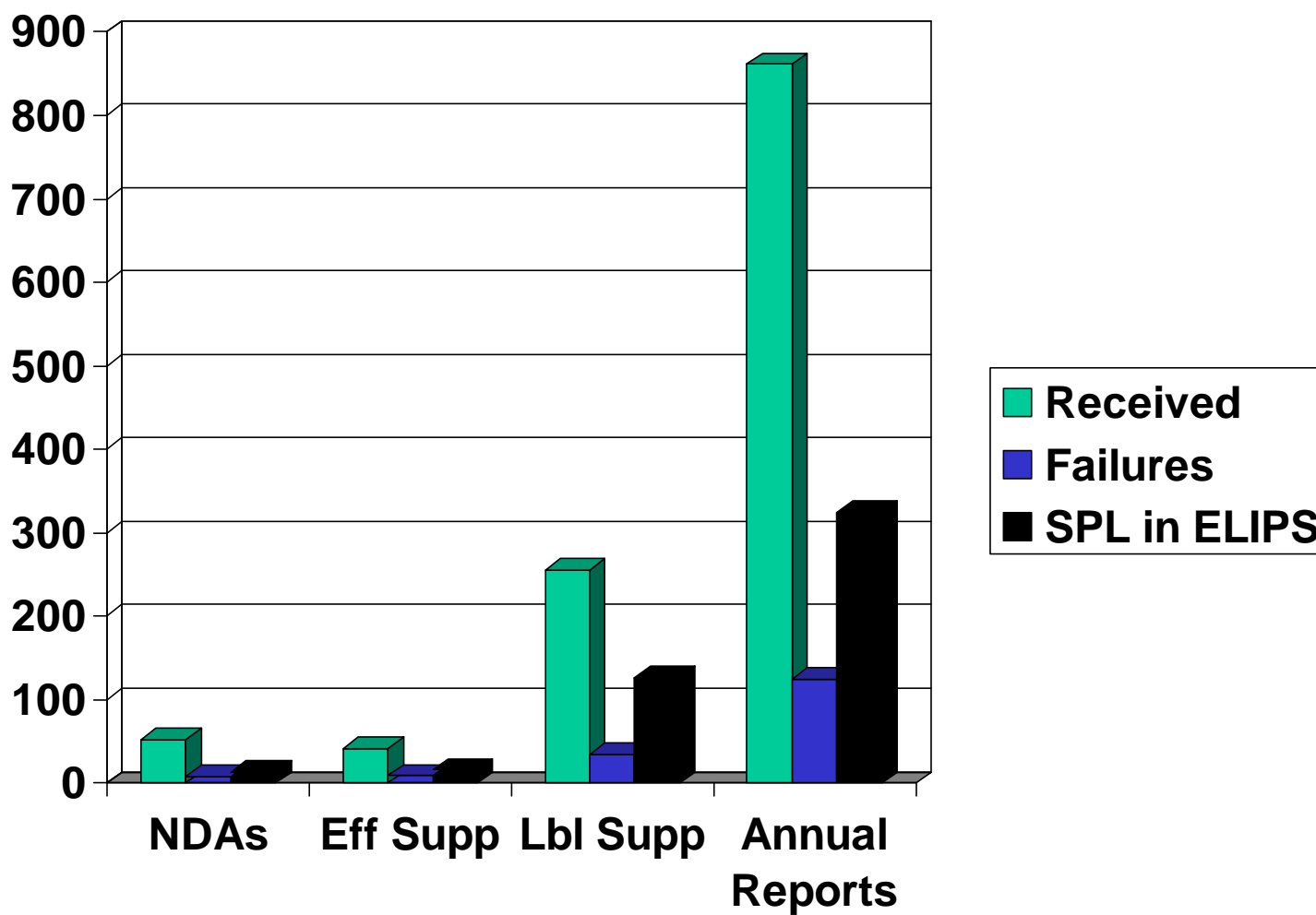
3483 potential SPL submissions received

- 2274 submissions to Generic Drugs
- 1209 submissions to OND

973 attempted to provide SPL

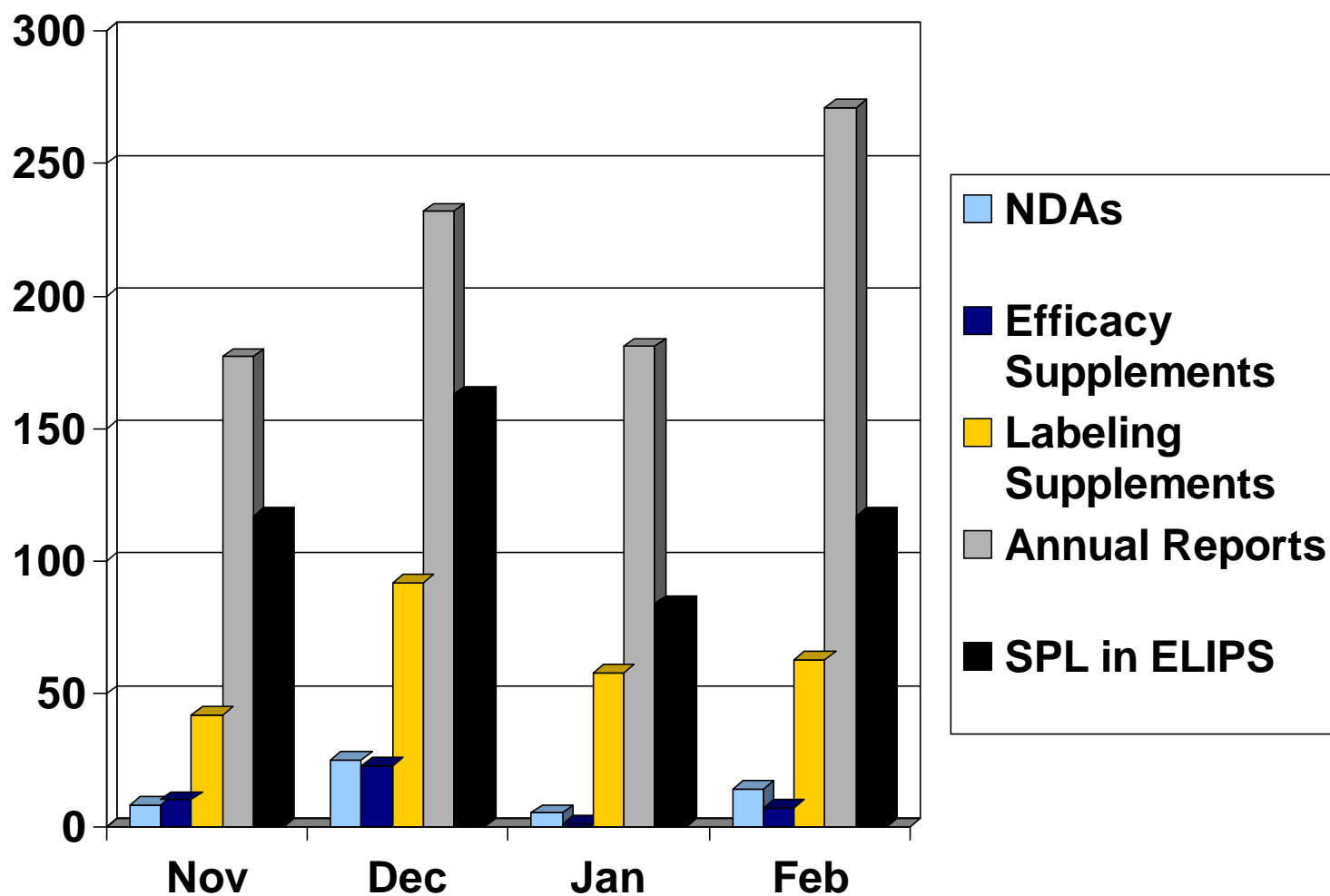- 54% (657/1209) of the OND submissions
- 14% (316/2274) of the Generic Drug submissions

Progress Report - OND

Progress Report - OND

Physician's Labeling Rule and SPL

- Highlights

- Table of Contents

- Data Elements

- Recent Major Changes

Physician's Labeling Rule and SPL

- ## Highlights

half page summary providing immediate access to information that healthcare professionals most commonly refer to and view as most important

- ## Table of Contents

reference to all the information in the label and serves as a navigational tool for quickly finding specific information

- ## Reorganization

 - most important information for prescribers is up front

 - Consolidated risk information

 - New sections

 - Patient counseling information and patient labeling is included to enhance communication between healthcare professionals and patients

PLR Implementation Schedule

Affected Submissions	Conformance Required
Submitted on or after 30-JUN-2006	Time of submission
Pending on 30-JUN-2006 or approved 0-1 yr prior	June 30, 2009
Approved 1-2 years prior to 30-JUN-2006	June 30, 2010
Approved 2-3 years prior to 30-JUN-2006	June 30, 2011
Approved 3-4 years prior to 30-JUN-2006	June 30, 2012
Approved 4-5 years prior to 30-JUN-2006	June 30, 2013
Prior to June 30, 2001	Voluntarily

Contacts

www.fda.gov/oc/datacouncil/spl.html

Questions

- Lonnie Smith (General)   301-796-0626
- Koung Lee (Generic Drugs)   301- 827-5846

Program Management

- Rachel Behrman, Program Sponsor
- Randy Levin, SRS Sponsor
- Jim Shugars, IT Program Manager
- Lisa Stockbridge, Business Program Manager
- Colleen Ratliffe, SRS IT Project Manager